

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

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CENTER FOR SCIENCE IN THE PUBLIC )  
INTEREST, et al., )  
) )  
Plaintiffs, )  
) )  
v. )  
) )  
FOOD AND DRUG ADMINISTRATION )  
) )  
Defendant, )  
) )  
JULIAN M. WHITAKER, M.D., et al., )  
) )  
Defendant Intervenors )  


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Civil Action No. 03-1962 (RBW)

**ORDER**

This matter comes before the Court on the plaintiffs' Motion to Alter or Amend this Court's July 30, 2004 Order and accompanying Memorandum Opinion issued on August 6, 2004 ("Pls.' Mot."), pursuant to Federal Rule of Civil Procedure 59(e) on the ground that the Court's opinion is based on an incorrect factual premise. Also before the Court at this time are: (1) the plaintiffs' Memorandum in Support of Plaintiffs' Motion to Alter or Amend this Court's July 30, 2004 Order ("Pls' Mem."); (2) the defendant's Opposition to Plaintiff's Motion to Alter or Amend this Court's July 30, 2004 Order ("Def.'s Opp'n"); (3) the defendant intervenors' Opposition to Plaintiff's Motion to Alter or Amend this Court's July 30, 2004 Order ("Def. Intervenor's Opp'n"); and plaintiffs' Reply Memorandum in Support of Motion to Alter or Amend the Court's July 30, 2004 Order ("Pls.' Reply"). For the following reasons, this Court denies the plaintiffs' motion.

## I. Background

This case arose from the plaintiffs' challenge pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), to an interim "regulatory guidance . . . issued by the Food and Drug Administration ("FDA")" in July 2003 ("July Guidance"). Complaint for Declaratory and Injunctive Relief ("Compl.") ¶ 1. The plaintiffs maintain that the July Guidance permits representations to be made about the alleged health benefit of foods without establishing scientific evidentiary support, and without complying with the procedural requirements and substantive standards of the Nutritional Labeling and Education Act of 1990 ("NLEA"), 21 U.S.C. § 343(r)(1). August 6, 2004 Opinion at 1. Consequently, the plaintiffs believe that their members will suffer "irreparable injury" as a result of being deprived of the food labeling protection mandated by the NLEA and secured by a prior FDA regulation. Compl. ¶¶ 1, 37. The defendant asserted that this Court lacked subject matter jurisdiction and moved to dismiss this action pursuant to Federal Rule of Civil Procedure 12(b)(1). August 6, 2004 Opinion at 1. This Court granted the defendant's motion to dismiss, concluding that the plaintiffs lacked standing to pursue this matter and that their claims were not ripe for judicial resolution. Id. at 2. This Court held that the plaintiffs failed to demonstrate an injury in fact resulting from the July Guidances and, therefore, did not establish Article III standing. Id. at 9. This finding was based on the Court's conclusion that the plaintiffs' claims were not supported by evidence that the plaintiffs or their members relied on a misleading qualified health claim and were injured as a result of such a claim, which is necessary to demonstrate an injury in fact. Id. Moreover, the Court concluded that any harm the plaintiffs were alleging was speculative because they had not identified any situations where the July Guidance was used to approve labeling and thus, this Court held that

their claims were not ripe for adjudication. Id. at 6.

In the current motion before the Court, the plaintiffs contend that a central premise of this Court's August 6, 2004 opinion was that the FDA had not yet approved a qualified health claim under the July Guidance. Pls.' Mem. at 2. The plaintiffs allege, however, that the FDA has approved a qualified food health claim under the July Guidance. Id. The plaintiffs contend that "on March 9, 2004, the FDA approved a health claim for walnuts and reduced risk of coronary heart disease " pursuant to the standards in the July Guidance. Id. Hence, the plaintiffs opine that a key factual premise for the Court's decision was erroneous. Id. The defendant maintains, however, that the plaintiffs are "mistaken," as the walnut health claim was evaluated under the FDA's December 2002 Guidance, which is not at issue in this lawsuit. Def.'s Opp'n at 2. According to the defendant, the source for plaintiffs' argument was an inaccurate FDA press release, instead of the "primary documents relevant to FDA's decision on the walnuts claim." Id.; Def.'s Opp'n at Exhibit ("Ex.") 1. Nonetheless, the defendant posits that even if the walnut claim was evaluated under the July Guidance, the plaintiffs' current motion must be denied because they cannot overcome the standing and ripeness impediments. Def.'s Opp'n at 5. In their reply, the plaintiffs assert that they relied on both the press release and the approval letter. Pls.' Reply at 2.

## **II. Standard of Review**

A Rule 59(e) motion to alter or amend a judgment after dismissal is a disfavored remedy which, although left to the court's discretion, should be granted only under extraordinary circumstances. See Turkmani v. Republic of Bol., 273 F. Supp. 2d 45, 49 (D.D.C. 2002) (citations omitted); Niedermeier v. Office of Max S. Baucus, 153 F. Supp. 2d 23, 28 (D.D.C.

2001) (citing Anyanwutaku v. Moore, 151 F.3d 1053, 1057 (D.C. Cir. 1998)). The reasons for reconsidering a judgment are "an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error to prevent manifest injustice." United States v. York, 890 F. Supp. 1117, 1140 (D.D.C. 1995) (citations omitted), rev'd on other grounds, 112 F.3d 1218 (D.C. Cir. 1997). A motion to reconsider a judgment dismissing one's claim is "not simply an opportunity to reargue facts and theories upon which a court has already ruled." Turkmani, 273 F. Supp. 2d at 49 (citing New York v. United States 880 F. Supp. 37, 38 (D.D.C. 1995)). Thus, the movant bears the burden to "clearly establish [a] manifest error of law or fact." United States v. Western Elec. Co., 690 F. Supp. 22, 25 (D.D. C. 1988) (citations omitted). Only if the moving party presents "new facts or a clear error of law which compel a change in the Court's ruling will the motion to reconsider be granted." New York, 880 F. Supp. at 38.

### **III. Legal Analysis**

The plaintiffs' motion fails to meet the requirements of Rule 59(e). There has been no change in the applicable law, nor has any new evidence become available since the plaintiffs filed their complaint. The plaintiffs assert that the July 30, 2004 Order and corresponding opinion should be altered because they rely on an incorrect factual premise— that no labeling has been approved pursuant to the July Guidance. Pls.' Mem. at 3. The plaintiffs argue that they have standing to pursue this matter based on the "imminent threat" their members face by not being able to rely on food labels for accurate information. Further, the plaintiffs assert that if a qualified food health claim has been evaluated under the July Guidance, regardless of when the evaluation occurred, the Court's "concern that review of 'a non-binding, pre-enforcement policy' should await application in 'a concrete setting'" has been alleviated and their claim cannot be said

to merely address a possibility of future injury. Pls.' Mem. at 4. Thus, plaintiffs assert that their claim is ripe for adjudication and this Court's prior conclusion that their alleged injuries were too speculative to be ripe for review is erroneous. Pls.' Reply at 4. However, assuming, without deciding, that the FDA reviewed the walnut claim under the July Guidance, the plaintiffs' current motion must nonetheless fail as a matter of law.

When a court reviews claims for ripeness or standing to pursue a claim, such review is conducted based on the facts that existed at the time the complaint was filed. See Arizonans for Official English v. Ariz., 520 U.S. 43, 67 (1997) ("To qualify as a case fit for federal-court adjudication, [a] . . . controversy must be extant at all stages of review."); Lujan v. Defenders of Wildlife, 504 U.S. 555, 569 n.4 (1992) (explaining that "[t]he existence of federal jurisdiction ordinarily depends on facts *as they exist when the complaint is filed*" – later fulfillment of the standing requirements does not give plaintiffs standing.)(emphasis in original); Sierra Club v. Dombeck, 161 F. Supp. 2d 1052, 1062 (D. Ariz. 2001) ("[r]ipeness is determined at the time of the filing of the complaint"); Natural Law Party of the United States of Am. v. Fed. Election Comm'n, 111 F. Supp. 2d 33, 40 (D.D.C. 2000) ("[s]tanding is determined at the time the complaint is filed"). Here, the plaintiffs filed their complaint on September 3, 2003. According to the plaintiffs' motion to alter or amend, the walnut claim was not approved until March 8, 2004, more than six months after the complaint was filed. Pls.' Mem. at 2. Therefore, because the approval occurred after the complaint was filed, the Court did not err in refusing to give the March 9, 2004 approval, or any other subsequent approval, consideration in its standing and ripeness analysis. See, e.g., Sierra Club, 161 F. Supp 2d at 1062; Natural Law Party, 111 F. Supp. 2d at 40.

**IV. Conclusion**

Based on the foregoing analysis, it is clear that the plaintiffs have failed to satisfy their burden of establishing that the dismissal of this case was based on a clear error of fact or law, which must be demonstrated for this Court to have a basis to alter or amend its decision to dismiss this case. Consequently, this Court must deny the plaintiffs' motion. Accordingly, it is hereby this 17th day of September, 2004

**ORDERED** that the plaintiffs' motion to alter or amend the Court's July 30, 2004 order is **DENIED**.

**SO ORDERED,**

REGGIE B. WALTON  
United States District Judge